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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,422	02/27/2004	Boris Y. Shekunov	FER-14668.001	5255

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RANKIN, HILL & CLARK LLP
925 EUCLID AVENUE, SUITE 700
CLEVELAND, OH 44115-1405

EXAMINER	
DRODGE, JOSEPH W	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/789,422	SHEKUNOV ET AL.	
	Examiner	Art Unit	
	Joseph W. Drodge	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 February 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9,11-14 and 17-29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11-14 and 17-29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-9 ,11-14 and 17-29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sievers et al patent 5,639,441 in view of Beckman et al patent 6,184,270 and Subramaniam et al patent 6,113,795.

Sievers et al disclose producing of particles [as in claims 10 and 15] comprising providing supercritical fluid, 1st solvent soluble in such fluid, 2nd insoluble solvent, the 2nd solvent optionally being partially soluble in the 1st solvent, and solute, contacting these together to form a solution, then contacting the solution with supercritical fluid to extract 1st solvent from the solution and precipitate the solute in the form of particles suspended in the 2nd solvent (all disclosed at column 5, line 66-column 6, line 61, column 6, line 66-column 7, line 5 indicate that the solution of solvents and solute are formed before contacting with supercritical fluid).

The solute contains a biologically active substance as in claims 2 and 11 (column 5, lines 22-36). The supercritical fluid is carbon dioxide as in claim 3 (column 6, line 44). There may be plural solutes as in claim 4 (column 5, lines 36-40). There is also a 2nd solute comprising a polymer, wax or lip as in claims 5 and 12 (column 5, line 37). The 1st solvent may an alcohol or acetone organic solvent as in claims 6,13 and 7 (column 5, lines 66-67 and column 6, line 51) while the 2nd solvent is water (column 6, lines 57-59) as in claim 8. The particle size is from 10 nm to 10 microns (column 6, liknes 33-36) for claims 9 and 14.

Both of the fluids/solvents may be or include different supercritical fluids or liquids (column 6, lines 49-52). This portion of text in combination with text of column 7, lines 15-20 gives the option of one of the supercritical fluids/liquids entering the gaseous phase and such fluid/liquid and/or co-solvent thereof (column 6, lines 53-56) precipitating a gas-borne dispersion or suspension of particles while the other supercritical fluid or liquid remains, at least initially in

supercritical state. Such dispersion may, in a preferred embodiment comprise particles of solid or liquid and may comprise the dissolved substance in solution or suspension, optionally in an organic solvent such as methanol (column 6, lines 17-24 supported by column 5, line 66-column 6, line 4 and column 6, lines 49-56).

The claims also require that the particles are precipitated to form a suspension in second solvent and separated from the first solvent dissolved in supercritical fluid. Sievers apparently discloses such precipitation and formation of particles to occur as pressures are rapidly lowered and one of the fluids (supercritical fluids) enters the gaseous phase to initiate precipitation and formation of particles (column 7, lines 15-20). Sievers does not state that all of the supercritical fluids enter a gaseous phase. Further, Sievers also teaches that the first fluid may be chosen to comprise water, methanol or ethanol (column 6, lines 49-51), with such water, methanol or ethanol being in a supercritical state (column 6, lines 37-44). Fluids such as methanol and water are also disclosed as "mutually soluble", hence constitute solvents and supercritical fluids, simultaneously. Sievers further discloses that the second fluid may be chosen to comprise another supercritical fluid or liquid with such fluid or liquid, preferably being carbon dioxide or a mixture of carbon dioxide and an additional supercritical fluid/ethanol or fluoroform (column 6, lines 41-53). The carbon dioxide mixture is depicted as having advantages of low chemical reactivity, safety and relatively low cost.

The claims all differ in requiring that the separation of particulate suspension from solvent be by way of flowing solvent with supercritical fluid out of the extraction chamber via a backpressure regulator and separately flowing particulate suspension from extraction chamber to

a collection vessel, that can be isolated from the chamber and subsequently draining the vessel of particulates.

Beckman teaches to flow solvent and fluid from extraction chamber 20 via backpressure regulation valve system a/V4/b/RV to a fume hood or recycling and separately flowing the particulate sample via another leg of 3 way valve V4 to collection vessel where particles are later removed/drained (figure 2A and column 7, line 61-column 8, line 5). Subramanian teaches from extraction/precipitation vessel 32, the particles being flowed to separation vessel 54 and solvent and supercritical fluid flowing through a pressure-regulating valve system to separating vessel 44 that effects separation of solvent from supercritical fluid. It would have been obvious to one of ordinary skill in the art to have augmented the Sievers method or system with the solvent, fluid and particulate suspension system of Beckman and Subrimamian in order to facilitate recycling of both the solvent and supercritical fluid for re-use in a high-volume industrial process for producing nanoparticles or microparticles of either pharmaceuticals or coatings.

Regarding dependent claims, Sievers discloses biologically active substance for claims 2,18 and 11 (column 5, lines 22-36), carbon dioxide for claims 3 and 19 (column 6, line 44), plural solutes for claims 4 , 20 and 21,(column 5, lines 36-40), 2nd solute for claims 5,21,27 and 12 (column 5, lines 37). The first solvent may be an alcohol or acetone for claims 6, 7,22,23,28 and 13 (column 5, lines 66-67 and column 6, line 51), with 2nd solvent being water (column 6, lines 57-59) as in claims 24 and 8. the particle size is from 10 nm to 10 microns for claims 9,25,29 and 14 (column 6, lines 33-36).

The Declaration under 37 CFR 1.132 filed 18 February 2008 is sufficient to overcome the rejection of claims 1-9,11-14 and 17-29 based upon Chattopadhyay et al patent 7,083,748 as supported by it's provisional.

Applicant's arguments with respect to claims 1-9,11-14 and 17-29 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Drodge at telephone number 571-272-1140. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David Roy Sample, can reached at 571-272-1376. The fax phone number for the examining group where this application is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either private PAIR or Public PAIR, and through Private PAIR only for unpublished applications. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JWD

March 26, 2008

/Joseph W. Drodge/
Primary Examiner, Art Unit 1797